

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the adoption of New)	NOTICE OF PUBLIC HEARING ON
Rules I through IX, the amendment of)	PROPOSED ADOPTION,
ARM 37.110.201, 37.110.238,)	AMENDMENT, AND
37.110.239, 37.110.243, and the)	REPEAL
repeal of ARM 37.110.202,)	
37.110.203, 37.110.204, 37.110.206,)	
37.110.207, 37.110.208, 37.110.209,)	
37.110.210, 37.110.212, 37.110.213,)	
37.110.214, 37.110.215, 37.110.216,)	
37.110.217, 37.110.218, 37.110.219,)	
37.110.220, 37.110.221, 37.110.222,)	
37.110.223, 37.110.225, 37.110.226,)	
37.110.227, 37.110.228, 37.110.229,)	
37.110.230, 37.110.231, 37.110.232,)	
37.110.236, 37.110.240, 37.110.241,)	
37.110.242, 37.110.252, 37.110.253,)	
37.110.254, 37.110.255, 37.110.256,)	
37.110.257, 37.110.258, and)	
37.110.259 pertaining to updating the)	
Montana retail food establishment)	
rules)	

TO: All Concerned Persons

1. On July 21, 2014, at 10:00 a.m., the Department of Public Health and Human Services will hold a public hearing in the auditorium of the Department of Public Health and Human Services Building, 111 North Sanders, Helena, Montana, to consider the proposed adoption, amendment, and repeal of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact Department of Public Health and Human Services no later than 5:00 p.m. on July 14, 2014, to advise us of the nature of the accommodation that you need. Please contact Kenneth Mordan, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be adopted provide as follows:

NEW RULE I INCORPORATION BY REFERENCE (1) The Department of Public Health and Human Services (department), except as otherwise provided in this chapter, adopts and incorporates by reference the following publication: "Food Code, 2013, Recommendations of the United States Public Health Service, Food and Drug Administration" published by National Technical Information Service, Publication PB2013-110462, ISBN 978-1-935239-02-4, November 3, 2013. This publication may be reviewed online at: <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm>; or by contacting DPHHS-FCSS, 1400 Broadway Street, Helena, MT 59620. This publication is being adopted with modifications and additions as described in [New Rule I through IX].

(a) Chapter 1: Purpose and Definitions. Additions and modifications have been made to this chapter as described in [New Rule II].

(b) Chapter 2: Management and Personnel. Additions have been made to this chapter as described in [New Rule III].

(c) Chapter 3: Food. This chapter has been adopted with no modifications.

(d) Chapter 4: Equipment, Utensils, and Linens. This chapter has been adopted with no modifications.

(e) Chapter 5: Water, Plumbing, and Waste. Additions have been made to this chapter as described in [New Rule VI].

(f) Chapter 6: Physical Facilities. An addition has been made to this chapter as described in [New Rule VII].

(g) Chapter 7: Poisonous or Toxic Materials. This chapter has been adopted with no modifications.

(h) Chapter 8: Compliance and Enforcement. Additions and modifications have been made to this chapter as described in [New Rule IX].

(i) Annexes 1 through 7 of the "Food Code, 2013, Recommendations of the United States Public Health Service, Food and Drug Administration" are excluded. These sections have not been adopted, but may be used as reference information for public health purposes.

(2) The department, except as otherwise provided in this chapter, adopts and incorporates by reference the following publication: "Food and Consumer Safety (FCS) Circular 1-2012" for nonpublic water systems serving food establishments, including temporary food establishments. A copy of FCS Circular 1-2012 may be obtained from the Department of Public Health and Human Services, Food & Consumer Safety Section, P.O. Box 202951, Helena, MT 59620-2951. The FCS Circular 1-2012 is also available on the department's web site at www.fcss.mt.gov.

AUTH: 50-50-103, MCA

IMP: 50-50-102, 50-50-103, 50-50-105, 50-50-107, 50-50-201, 50-50-301, 50-50-302, 50-50-304, MCA

NEW RULE II CHAPTER 1: PURPOSE AND DEFINITIONS The terms defined in this section are modifications or additions to the definitions described in this chapter of the 2013 Food Code:

(1) "Adulterated" means the same as determined in 50-31-202, MCA instead of the "Adulterated" definition in section 1-201.10 of the November 3, 2013 model

document of food regulations promulgated by the United States Food and Drug Administration (Food Code).

(2) "Bakery" means processing or packaging of baked goods described in 50-50-102(1), MCA for sales or service directly to consumers.

(3) "Catering kitchen" means the activity of providing food wholly or in part owned by the caterer for a specific event at a location other than the licensed food establishment or food service establishment, as defined in 50-50-102(7)(a) and (b), MCA, on a contractual, prearranged basis to a specific subset of the public, such as invited guests to a wedding or similar celebration, or to participants in an organized group or activity. A catering kitchen is not the same activity as a contract cook.

(4) "Certified Food Protection Manager" (CFPM) means an individual who operates a food establishment or manages a food establishment who has successfully completed a test through an accredited program required under section 2-102.12 (A) of the Food Code.

(5) "Department" means the Montana Department of Public Health and Human Services.

(6) "Food Code" means the November 3, 2013 model document of food regulations promulgated by the United States Food and Drug Administration.

(7) "Food establishment" means the following:

(a) includes in section 1-201.10 (1) of the Food Code, any and all licensable establishments stated in Title 50, chapter 50, MCA;

(b) does not include in section 1-201.10 (3) of the Food Code, any and all food provider exclusions stated in Title 50, chapter 50, MCA;

(c) in section 1-201.10 (3)(f) of the Food Code, the term "small family day-care provider" actually means a day-care provider not required to be licensed by the department as a day-care center, under 52-2-721(1)(a), MCA; and

(d) in section 1-201.10 (3)(f) of the Food Code; a bed-and-breakfast operation actually means a bed-and-breakfast establishment that meets the definition in 50-51-102(1), MCA. Bed-and-breakfast establishments must meet food safety rules required in ARM 37.111.312 through 37.111.334.

(8) "Food manufacturing" means the same as 50-50-102(19), MCA, but for the purposes of license subtypes, should be on-site food processing for sales or service to the public, which includes drinking water vending machines and beverage ice production, packaging, or both.

(9) "Food service" means the same as 50-50-102(7), MCA, but for the purposes of license subtypes, should only be the sales or service of food to the public that is not processed on-site.

(10) "Legal licensee" means the same as "permit holder."

(11) "License" means the same as "permit."

(12) "License subtype" means one or more of the following food establishments: bakery, catering kitchen, food service, food manufacturing, meat shop, mobile food establishment, perishable food dealer, produce, school, tavern, or water hauler.

(13) "License type" means a food establishment at a fixed (nonmobile or permanent) location, mobile food establishment, or temporary food establishment.

(14) "Meat shop" means the same as 50-50-102(10), MCA, but is the processing or packaging of meat or poultry for sales or service to the public.

(15) "Mobile food establishment" means:

(a) A food establishment where food is served or sold from a motor vehicle, portable structure, nonmotorized cart, movable vehicle such as a push cart, trailer, or boat that periodically or continuously changes location and requires a servicing area to accommodate the unit for cleaning, inspection, and maintenance, as specified in paragraphs 5-402.14, 6-101.11, and 6-202.18.

(b) Mobile food establishment does not include a motor vehicle used solely to transport or deliver food by a motorized carrier regulated by the state or federal government or a concession stand designed to operate as a temporary food establishment.

(16) "Perishable food" means fruits, vegetables, and foods that require time/temperature control for safety (formerly known as potentially hazardous foods).

(17) "Perishable food dealer" means the same as 50-50-102(12), MCA, which is an operation that is in the business of purchasing and selling fruits, vegetables, and foods that require time/temperature control for safety (formerly known as potentially hazardous foods).

(18) "Potentially hazardous food" means time/temperature control for safety food.

(19) "Processing" means the same as "preparation" of food through one or more methods including: assembling, baking, bottling, brewing, canning, coating, cooking, cutting, dicing, distilling, drying, extracting, fermenting, freezing, grinding, heating, infusing, mixing, packaging, reheating, repackaging, pickling, slicing, smoking, stuffing, or other food treatment or food preservation method.

(20) "Produce" means fruits, vegetables, or grains sold directly to consumers in their natural or processed states.

(21) "Regulatory authority" means the department, the local board of health, the local health officer, or the local sanitarian, instead of the "regulatory authority" definition in section 1-201.10 of the Food Code.

(22) "School" means a building or structure or portion thereof occupied or used at least 180 days per year for the teaching of individuals, the curriculum of which satisfies the basic instructional program approved by the board of public education for pupils in any combination of kindergarten through grade 12, but excludes home schools as that term is defined in 20-5-102(2)(e), MCA. For purposes of this licensing subtype, in general, a school is also a learning institution that participates in the federal National School Lunch Program, under 7 CFR 210 of the Code of Federal Regulations.

(23) "Tavern, bar, brewery, winery, distillery, or saloon" means the sale or service of alcoholic beverages with or without beverage ice. This licensing subtype does not include on-site food manufacturing or food service, as defined in this section of the rules.

(24) "Temporary food establishment" means food establishment that operates at a fixed location for a period of no more than 14 consecutive days in conjunction with a single event or celebration, instead of the "Temporary food establishment" definition in section 1-201.10 of the Food Code.

(25) "Water hauler" means the same as 50-50-102(20), MCA.

AUTH: 50-50-103, MCA

IMP: 20-5-102, 50-50-102, 50-50-103, 50-50-104, 50-50-201, MCA

NEW RULE III CHAPTER 2: MANAGEMENT AND PERSONNEL (1) The following additions have been made to section 2-102.12 of Chapter 2.

(a) A one-year, phase-in period will apply to affected establishments to have a Certified Food Protection Manager, and the one-year period will begin from the date new rules are adopted.

(b) After the one-year, phase-in period, new legal licensees required to have a Certified Food Protection Manager must have a Certified Food Protection Manager within 90 days of issuance of a new license.

(c) After the one-year, phase-in period, existing legal licensees required to have a Certified Food Protection Manager must have a Certified Food Protection Manager within 30 days of losing their Certified Food Protection Manager.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

NEW RULE IV CHAPTER 3: FOOD (1) This chapter has been adopted with no modifications.

AUTH: 50-50-103, MCA

IMP: 50-50-102, 50-50-103, 50-50-301, 50-50-302, 50-50-303, 50-50-304, MCA

NEW RULE V CHAPTER 4: EQUIPMENT, UTENSILS, AND LINENS

(1) This chapter has been adopted with no modifications.

AUTH: 50-50-103, MCA

IMP: 50-50-102, 50-50-103, 50-50-301, 50-50-302 MCA

NEW RULE VI CHAPTER 5: WATER, PLUMBING, AND WASTE

(1) Additions have been made to section 5-101.11 (B) of this chapter for nonpublic water systems.

(2) A nonpublic water supply system must meet the requirements of Food and Consumer Safety (FCS) Circular 1-2012 when:

(a) the water supply is constructed after the effective date of this rule;

(b) significant modifications are made to the water system; or

(c) the local regulatory authority determines compliance with FCS Circular 1-2012 is necessary to meet the requirements of this subchapter.

(3) An establishment using a nonpublic water supply system must have drinking water samples analyzed for coliform bacteria as follows:

(a) Sampling for coliform bacteria must be done before initial licensing, and at least in two separate months of each calendar year that the establishment operates.

(b) The sampling schedule must include collection when the water source is most likely to be contaminated, such as during April through June, September through October, during high, ground-water season, or as directed by the local regulatory authority.

(c) The local regulatory authority may require the establishment to sample:

- (i) monthly;
- (ii) in months the establishment operates; or
- (iii) if an inspection, sampling results, or an event indicates the water source is at high risk of contamination.

(d) The local regulatory authority may return the establishment to the sampling frequency stated in (3)(a), if an examination of the drinking water system by the local regulatory authority indicates the system is no longer at high risk of contamination.

(4) An establishment using a nonpublic water supply system must have a water sample analyzed for total nitrates before initial licensing and at least every three years the establishment is operating.

(5) After shock disinfection of the system, and the disinfectant is no longer detected in the system, a sample for coliform bacteria must be collected for analysis at least three to five days after the disinfectant is no longer detected in the system.

(6) Water samples must be analyzed by a laboratory licensed and certified for drinking water analysis by the state of Montana.

(7) The establishment must report water sampling test results to the local regulatory authority in a format acceptable to the local regulatory authority within five days of receiving the results, except as required in (9)(c) and (11)(d).

(8) The establishment must keep test results readily available for inspection purposes on the premises of the licensed establishment for at least five years.

(9) If coliform bacteria are detected in a nonpublic water system routine sample, the establishment must:

(a) collect at least four additional or repeat samples within 24 hours of notification of the contamination at the following system locations:

- (i) site of the original contaminated routine sample;
- (ii) upstream from the contaminated routine sample;
- (iii) downstream from the contaminated routine sample; and
- (iv) at the source of the drinking water supply system, before the distribution plumbing; or

(v) as directed by the local regulatory authority.

(b) collect at least five samples during the month following a detection of coliform bacteria in any routine sample; and

(c) notify the local regulatory authority of the test results within 48 hours of receiving them.

(10) If coliform bacteria are detected in a repeat sample, the establishment must:

(a) take appropriate corrective action to eliminate the condition causing the positive test results; and

(b) post an advisory sign or placard regarding the test results in a conspicuous place for public viewing at each point of entry, or as directed by the local regulatory authority.

(11) If fecal coliform bacteria, *Escherichia coli*, or both are detected in a routine sample or repeat sample, the establishment must:

(a) immediately stop using the water source;

(b) provide a temporary source of safe water in accordance with (17);

- (c) implement appropriate corrective actions; and
- (d) notify the local regulatory authority of the test results within 24 hours of receiving them.

(12) If an establishment fails to take the required samples following the detection of coliform bacteria, or the laboratory fails to test for fecal coliform bacteria or *Escherichia coli* in coliform positive samples, the establishment must follow corrective actions as specified in (13).

(13) For nonpublic water systems, appropriate corrective actions must be implemented in a timely manner to eliminate the condition or conditions that resulted in the positive test result(s), which may include, but not be limited to: shock disinfection of the entire water system and replacement or repair of the water system by a date set by the local regulatory authority when:

- (a) A water sample exceeds a maximum contaminant level as specified in ARM Title 17, chapter 38, subchapter 2;
- (b) The water system does not have the capacity to provide the quantity needed for drinking, food processing, personal hygiene, or cleaning;
- (c) After examination of the water system, the local regulatory authority provides a written report to the operator or person-in-charge that the water system is at high risk of contamination;
- (d) A pathogenic microorganism is detected in a sample; or
- (e) A confirmed disease outbreak is linked with the water system.

(14) When a water system is replaced or repaired, the water system must be shock disinfected before the system is placed into service.

(15) The local regulatory authority shall issue a restricted-use order to an establishment using a nonpublic water supply when:

- (a) Fecal coliform or *Escherichia coli* is detected in a nonpublic water system sample;
- (b) Total nitrate level is greater than 10 milligrams per liter in a nonpublic water system sample;
- (c) Maximum contaminant levels exceed parameters specified in ARM Title 17, chapter 38, subchapter 2;
- (d) A pathogenic microorganism is detected; or
- (e) A confirmed disease outbreak is linked with the water system.

(16) An establishment subject to a restricted-use order must provide and use a temporary source of potable water as described in (17) for consumers and staff for drinking, food processing, personal hygiene and cleaning, or immediately discontinue operations.

(17) With approval from the local regulatory authority, an establishment may provide potable water on a temporary basis using one or more of the following:

- (a) Bottled or packaged potable water from a department-licensed wholesale or retail food establishment, if the water is dispensed directly from the original container;
- (b) Water from a Department of Environmental Quality (DEQ)-approved public water supply that meets the requirements of ARM Title 17, chapter 38, subchapters 1, 2, 3, and 5, stored in a clean, sanitized, and covered potable water container or holding tank;
- (c) Water delivered by a department-licensed potable water hauler;

(d) If the water is contaminated with fecal coliform bacteria or Escherichia coli, water that has been boiled for at least one minute, and stored and served from a clean, sanitized, and covered container; or

(e) Other source approved by the local regulatory authority.

(18) If the local regulatory authority determines that boiling water will not provide adequate potable water, it may require an establishment to use another approved method for supplying water.

(19) An establishment subject to a restricted-use order must post an advisory sign or placard regarding the restricted-use order in a conspicuous place for public viewing at each point of entry, or as directed by the local regulatory authority.

(20) A water supply under a restricted-use order may not be used to make ice for food or beverages.

(21) An establishment subject to a restricted-use order may wash, rinse, and sanitize dishes, utensils, and equipment using the affected water system, if using an approved chemical disinfectant or dish machine that reaches 180 degrees Fahrenheit (82 degrees Celsius) during the final rinse cycle, or as directed by the local regulatory authority.

(22) A restricted-use order may be cancelled by the local regulatory authority after:

(a) Laboratory sampling demonstrates that the water supply is safe;

(b) Water system plumbing is completely flushed with cold water for at least five minutes; and

(c) Food-contact surfaces and equipment directly and indirectly connected to the water system must be cleaned and sanitized prior to use including, but not limited to: post-mix carbonated beverage machines, spray misters, coffee makers, tea urns, ice machines, glass washers, and dish machines.

(23) Additions have been made to section 5-303 of this chapter.

(24) Every mobile food establishment must be equipped with a gravity or pressurized water storage tank.

(25) The water storage tank in a mobile food establishment must be of adequate capacity, as required in section 5-103.11 (A), but no smaller than the following:

(a) a mobile food establishment that serves beverages or food or reheats processed foods must have a water storage tank with a capacity of at least 38 liters (10 gallons) for food employee handwashing;

(b) a food pushcart must have a water storage tank with a minimum capacity of 19 liters (5 gallons) for handwashing; and

(c) a mobile food establishment that processes food or beverages must have a water storage tank with a capacity of at least 151 liters (40 gallons) for handwashing, utensil washing, and sanitizing purposes.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

NEW RULE VII CHAPTER 6: PHYSICAL FACILITIES (1) Additions have been made to section 6-301.14 of this chapter.

(2) Food establishment operators may create and post their own signs or posters for the posting requirement.

(3) Signs or posters may also be obtained through the regulatory authority.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

NEW RULE VIII CHAPTER 7: POISONOUS OR TOXIC MATERIALS

(1) This chapter has been adopted with no modifications.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

NEW RULE IX CHAPTER 8: COMPLIANCE AND ENFORCEMENT

(1) Additions and modifications have been made to this chapter.

(2) In section 8-201.11, the regulatory authority may require properly prepared plans and specifications for review and approval before issuance of a new license to a new legal licensee at the change in ownership of an existing food establishment.

(3) Section 8-301.11 has not been adopted.

(4) Section 8-302.11 has not been adopted.

(5) Section 8-302.12 has not been adopted.

(6) Section 8-302.13 has not been adopted.

(7) Section 8-302.14 has not been adopted.

(8) Section 8-303.30 has not been adopted.

(9) Section 8-304.10 has not been adopted.

(10) Section 8-304.20 has not been adopted.

(11) Section 8-401.10 has not been adopted.

AUTH: 50-50-103, MCA

IMP: 50-50-102, 50-50-103, 50-50-104, 50-50-106, 50-50-107, 50-50-108, 50-50-109, 50-50-110, 50-50-201, 50-50-203, 50-50-205, 50-50-206, 50-50-207, 50-50-209, 50-50-210, 50-50-211, 50-50-212, 50-50-213, 50-50-301, 50-50-302, 50-50-304, 50-50-305, MCA

4. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.110.201 INTRODUCTION (1) This is a subchapter regulating retail food service establishments that serve prepared food and drink to the public, as provided in Title 50, chapter 50, MCA.

~~(2) This subchapter defines food, potentially hazardous food, food service establishment, mobile food service, semipermanent food service establishment, temporary food service establishment, regulatory authority, utensils, equipment, etc.; provides for the sale of only sound, safe, properly labeled food; regulates the sources of food; establishes sanitation standards for food, food protection, food service operations, food service personnel, food service and utensils, sanitary~~

~~facilities and controls, and other facilities; requires licenses for the operation of food service establishments; regulates the inspection of such establishments; provides for the examination and condemnation of food; provides for enforcement of this subchapter, and the fixing of penalties.~~

(3) ~~(2)~~ All retail food ~~service~~ establishments must comply with all appropriate building construction standards as set forth by 50-60-101, MCA and all applicable administrative rules as adopted by the Department of ~~Commerce~~ Labor and Industry in ARM Title 8 24.

AUTH: 50-50-103, MCA

IMP: 50-50-102, 50-50-103, 50-60-101, MCA

37.110.238 LICENSES (1) No person ~~shall~~ may operate a food ~~service~~ establishment who does not have a valid license issued by the department. Only a person who complies with the requirements of this subchapter ~~shall~~ will be entitled to receive or retain such a license. ~~Licenses are not transferable.~~ A valid license must be posted in every retail food ~~service~~ establishment.

(2) Any person desiring to operate a retail food ~~service~~ establishment ~~shall~~ must make written application for a license on forms provided by the department. ~~Such application must include the name and address of each applicant, the location and type of the proposed food service establishment.~~

(3) Prior to approval of an application for a license, the regulatory authority ~~or the local health department sanitarians shall~~ must inspect the proposed retail food ~~service~~ establishment to determine compliance with the requirements of this subchapter.

(4) The department will issue a license to the applicant if an inspection by a ~~state or local health officer or sanitarian~~ the regulatory authority reveals that the proposed retail food ~~service~~ establishment complies with all applicable requirements of this subchapter.

(5) The department may, after providing opportunity for hearing, ~~revoke~~ cancel a license for serious or repeated violations of any of the requirements of this subchapter or for interference with the department or other authorized persons in the performance of duty.

(6) Prior to ~~revocation~~ cancellation, the department will notify, in writing, the licensee of the specific reason(s) for which the license is to be ~~revoked~~ cancelled. The notice will further provide for the licensee the opportunity to request an administrative hearing in front of the department within ~~40~~ ten business days after the receipt of the notice. If no request for hearing is filed within the ~~40~~ ten-day period, the ~~revocation~~ cancellation of the license becomes final.

(7) The licensee may submit to the department an acceptable plan of correction within ~~40~~ ten business days after receiving the department's notice of ~~revocation~~ cancellation. Such an acceptable plan of correction will be a bar to canceling the license.

(8) A notice provided for in this rule is properly served when it is delivered to the holder of the license, or the person in charge, or when it is sent by registered or certified mail, return receipt requested, to the last known address of the holder of the license. A copy of the notice will be filed in the records of the department.

(9) The hearing provided for in this rule will be conducted by the department pursuant to Title 2, chapter 4, subchapter 6, MCA of the Montana Administrative Procedure Act regarding contested cases and ARM 37.5.117. The department ~~shall~~ will make a final finding based upon the complete hearing record and ~~shall~~ will sustain, modify, or rescind any notice or order considered in the hearing. The department will furnish a written report of the hearing decision to the licensee.

(10) Whenever a ~~revocation~~ cancellation of a license has become final, the holder of the ~~revoked~~ cancelled license may make written application for a new license.

(11) Obtaining the license referred to in (1) ~~of this rule~~ does not relieve the applicant from satisfying applicable requirements from other federal, state, or local agencies. These may include, ~~but are not limited to:~~

- (a) building code permits and inspections;
- (b) fire and life safety inspections;
- (c) private or public water supply system or sewage treatment systems permits or inspections; or
- (d) occupational health and safety requirements.

(12) The regulatory authority will assign a food establishment to a license type and subtype by assessing food processing procedures, food service, and utilizing the definitions in these rules.

(13) At the time of initial licensing and updated as needed, but no less than each licensing year, the regulatory authority will correctly assign a food establishment to one of four categories by evaluating the food processing and service procedures of the food establishment based on the criteria specified in Table 1:

Table 1
Food Establishment Complexity Categories

<u>Category</u>	<u>Establishment Complexity</u>
(1)	(i) only heat commercially processed time/temperature control for safety foods (TCS/potentially hazardous foods) for hot holding; (ii) process only non-TCS foods; (iii) no cooling TCS foods; (iv) establishments otherwise grouped in Category 2, but have shown through documentation to have achieved managerial control of foodborne illness risk factors; and (v) examples include: convenience stores, hot dog carts, coffee shops, and establishments that serve or sell only prepackaged, non-TCS foods.
(2)	(i) establishment has a limited menu; (ii) processed foods are immediately served or made-to-order; (iii) food operations may involve hot and cold holding of TCS foods, after processing or cooking; (iv) limited processing of TCS foods that require cooking, cooling, reheating, and the limited service of a few TCS foods; (v) establishments that would otherwise be grouped in Category 3, but have shown through historical documentation to have achieved managerial control of foodborne illness risk factors; (vi) newly licensed establishments that would otherwise be grouped in

	Category 1 are categorized here, until a history of managerial control of foodborne illness risk factors is documented; (vii) examples include: retail food stores, schools not serving a highly susceptible population, and quick-service operations.
(3)	(i) establishment has extensive menu and handling of raw ingredients; (ii) complex preparation including cooking, cooling, and reheating for hot holding involving many TCS foods; (iii) variety of processes require hot and cold holding of TCS food; (iv) establishments that would otherwise be grouped in Category 4, but have shown through historical documentation to have achieved managerial control of foodborne illness risk factors; (v) newly licensed establishments that would otherwise be grouped in Category 2 are categorized here, until a history of managerial control of foodborne illness risk factors is documented; (vi) examples include: full-service restaurant.
(4)	(i) establishments serving a highly susceptible population; (ii) engage in specialized processes, such as smoking, curing, reduced oxygen packaging, etc.; (iii) examples include: preschools, hospitals, nursing homes, and special processing requiring a variance.

AUTH: 50-50-103, MCA

IMP: 50-50-103, 50-50-201, 50-50-204, 50-50-205, 50-50-206, 50-50-207, 50-50-208, 50-50-209, 50-50-210, 50-50-211, 50-50-212, 50-50-213, 50-50-214, 50-50-215, MCA

37.110.239 INSPECTIONS (1) The local health officer, ~~or a registered~~ sanitarian, ~~or sanitarian-in-training~~ employed by or contracted with the local board of health shall perform an inspection of each retail food ~~service~~ establishment within the jurisdiction of the local board of health at least ~~twice~~ once every 12 months ~~unless that schedule is modified by signed agreement with the department.~~ Additional inspections of the food service establishment must be performed as often as necessary for the enforcement of this subchapter.

~~(2) The local health officer, local health department sanitarian or sanitarian-in-training, or an authorized representative of the department, after proper identification, must be permitted to enter any food service establishment at any reasonable time for the purpose of making inspections to determine compliance with this subchapter and must be permitted to examine the records of the establishment to obtain information pertaining to food and supplies purchased, received, or used, or to persons employed.~~

~~(3) Whenever an inspection of a food service establishment is made, the findings must be recorded on an inspection form authorized by the department. The inspection report form must summarize the requirements of this subchapter. Inspection remarks must be written to reference the item violated and must state the correction to be made. A copy of the completed inspection report form must be furnished to the person in charge of the establishment at the conclusion of the inspection. The completed inspection report form is a public document that must be~~

made available for public review or distribution upon payment of copying costs to any person upon request.

~~(4) The completed inspection report form must specify a reasonable period of time for the correction of the violations found and correction of the violations must be accomplished within the period specified, in accordance with the following provisions:~~

~~(a) All critical item violations must be corrected as soon as possible, but in any event, within 10 days following inspection. Critical items include the following:~~

~~(i) ARM 37.110.203(61); 37.110.204(1); 37.110.206(2), (4) and (7); 37.110.207(4), (5), (7), (8), (9), and (11); 37.110.208(1), (3), (6), (7) and (8)(d); 37.110.210(1), (4), (6) and (7)(e); 37.110.212(10) and (11); 37.110.213(9)(a); 37.110.215(1), (2), (3), (13)(d), (14), (15), (23), (24), (25), and (28); 37.110.217(1), (3) and (6); 37.110.218(1); 37.110.219(1), (2), (3) and (6); 37.110.221(3); 37.110.223(1), (4) and (5); 37.110.231(1), (2), (3), (5), (6), (7), (8) and (9); 37.110.232(10); 37.110.236(3), (8), (10) and (11); 37.110.240(4); 37.110.242(1); 37.110.252(1) and (2); 37.110.253(5); 37.110.254; 37.110.255; 37.110.256(3) and (4); and 37.110.257(3)(c) and (d);~~

~~(b) All other violations which are the remaining food establishment rules not mentioned in (4)(a) and (4)(a)(ii) must be corrected as soon as possible, but in any event, by the time of the next routine inspection;~~

~~(c) In the case of temporary food service establishments, all violations must be corrected within 24 hours.~~

~~(5) The inspection report must state that failure to comply with any time limits for corrections of critical item violations may result in cessation of food service operations.~~

~~(6) In the case of critical items, the local health officer, sanitarian, or sanitarian-in-training must conduct a follow-up inspection to check for correction compliance and record the results on an inspection form authorized by the department.~~

AUTH: 50-50-103, 50-50-301, 50-50-305, MCA

IMP: 50-50-103, 50-50-104, 50-50-203, 50-50-205, 50-50-206, 50-50-301, 50-50-302, 50-50-305, MCA

37.110.243 MINIMUM PERFORMANCE REQUIREMENTS FOR LOCAL HEALTH AUTHORITIES (1) To qualify for reimbursement under 50-50-305, MCA, a local board of health ~~must either~~ will perform inspections as specified in this subchapter or enter into a written, signed cooperative agreement with the department that establishes the duties and responsibilities of the local board of health and the department consistent with this subchapter, ~~or indicate in writing to the department that each food establishment within the jurisdiction of the local board will be inspected at least twice every 12 months as specified in ARM 37.110.239(1).~~

~~(2) Requests for cooperative agreements must contain the current risk analysis information required by the department.~~

~~(3) All local boards of health must meet the following criteria regardless of the existence or absence of a cooperative agreement:~~

(a) At least one sanitarian working with or for the local board of health must receive training from the department in standardized food service inspections techniques. The department is responsible for making training and standardization review available on a periodic basis;

(b) ~~The local board of health must ensure that the following are done by the local health officer, sanitarian, or sanitarian-in-training:~~

~~(i) If a preliminary inspection is required under ARM 37.110.241, the food service establishment is inspected for compliance with this subchapter within 10 days after receiving notice from the department or the establishment that such a preliminary inspection is needed;~~

~~(ii) Each food service establishment within the jurisdiction of the local board of health is inspected at least twice every 12 months, or on the schedule specified in a signed agreement with the department;~~

~~(iii) All the requirements of ARM 37.110.239 are complied with;~~

~~(iv) Quarterly inspection reports are submitted to the department within 10 days following the close of each quarter of the fiscal year (1st quarter-September 30; 2nd quarter-December 31; 3rd quarter-March 31; 4th quarter-June 30) on forms approved by the department; Reporting of inspection dates must be documented in a manner and frequency approved by the department.~~

~~(v) (c) All documentation of enforcement of this subchapter, including but not limited to inspection reports, consumer complaints, illness investigations, plans of correction, and enforcement actions, is retained for 5 five years and copies of the documentation are submitted or otherwise made available to the department upon request.~~

(4) A failure by the local board of health to meet all of its responsibilities under the cooperative agreement or under (3)(a), and (b), and (c) above may result in the withholding of funds from the local board reimbursement fund in an amount to be determined by the department.

AUTH: 50-50-103, 50-50-305, MCA

IMP: 50-50-104, 50-50-208, 50-50-214, 50-50-215, 50-50-301, 50-50-305, MCA

5. The department proposes to repeal the following rules:

37.110.202 PURPOSE is found on page 37-27153 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

37.110.203 DEFINITIONS is found on page 37-27154 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

37.110.204 FOOD SUPPLIES is found on page 37-27167 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.206 FOOD STORAGE AND PROTECTION is found on page 37-27171 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.207 FOOD PREPARATION is found on page 37-27174 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.208 FOOD DISPLAY AND SERVICE is found on page 37-27179 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.209 FOOD TRANSPORTATION is found on page 37-27184 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.210 FOOD EMPLOYEES is found on page 37-27185 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.212 MATERIALS FOR EQUIPMENT AND UTENSILS is found on page 37-27193 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.213 EQUIPMENT AND UTENSIL DESIGN AND FABRICATION is found on page 37-27195 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.214 EQUIPMENT INSTALLATION AND LOCATION is found on page 37-27198 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.215 EQUIPMENT AND UTENSIL CLEANING AND SANITATION is found on page 37-27201 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.216 EQUIPMENT AND UTENSIL STORAGE is found on page 37-27206 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.217 WATER SUPPLY is found on page 37-27207 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.218 SEWAGE is found on page 37-27209 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.219 PLUMBING is found on page 37-27210 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.220 TOILET FACILITIES is found on page 37-27211 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.221 HAND WASHING FACILITIES is found on page 37-27215 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

37.110.222 GARBAGE AND REFUSE is found on page 37-27216 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

37.110.223 INSECT AND RODENT CONTROL is found on page 37-27218 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

37.110.225 FLOORS is found on page 37-27221 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

37.110.226 WALLS AND CEILINGS is found on page 37-27222 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

37.110.227 CLEANING PHYSICAL FACILITIES is found on page 37-27223 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

37.110.228 LIGHTING is found on page 37-27223 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

37.110.229 VENTILATION is found on page 37-27224 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

37.110.230 DRESSING ROOMS AND LOCKER AREAS is found on page 37-27224 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.231 TOXIC MATERIALS is found on page 37-27225 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.232 PREMISES is found on page 37-27227 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.236 TEMPORARY FOOD SERVICE ESTABLISHMENTS is found on page 37-27233 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.240 EXAMINATION AND CONDEMNATION OF FOOD is found on page 37-27239 of the Administrative Rules of Montana.

AUTH: 50-50-103, 50-50-303, MCA
IMP: 50-31-509, 50-50-103, MCA

37.110.241 REVIEW OF PLANS is found on page 37-27240 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.242 SUSPECTED DISEASE TRANSMISSION: PROCEDURE is found on page 37-27241 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, 50-50-105, MCA

37.110.252 HIGHLY SUSCEPTIBLE POPULATION is found on page 37-27263 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.253 VARIANCES is found on page 37-27264 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.254 SUBMISSION OF A HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) PLAN is found on page 37-27265 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.255 CONTENTS OF A HACCP PLAN is found on page 37-27267 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.256 MOBILE FOOD SERVICE is found on page 37-27268 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.257 PUSHCARTS is found on page 37-27270 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.258 SEMIPERMANENT FOOD SERVICE ESTABLISHMENT is found on page 37-27271 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.259 PERISHABLE FOOD VENDING MACHINES is found on page 37-27271 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

6. STATEMENT OF REASONABLE NECESSITY

The Department of Public Health and Human Services (the department) is proposing to adopt new rules and is proposing amendments to the existing Retail Food Establishment Rules to update standards to the most recent scientific information, better align the rules with other states, and improve uniform application of food

safety principles throughout Montana. The proposed new rules and substantive amendments are specifically outlined below.

New Rule I

The department is proposing to adopt the referenced document with additions, modifications, and no modifications to specific chapters in the document, as described in New Rule I, and detailed in New Rules II through IX. The department is also proposing this rule because the referenced chapter represents the best accumulated knowledge for a uniform system of provisions that address the safety and protection of food offered at the retail level.

New Rule II

The department is proposing to modify and add to definitions in the adopted document to correspond with existing state law and clarify terms in the proposed rules.

New Rule III

The department is proposing to add a phase-in period for when establishments must have a trained food protection manager. The department is also proposing this rule because the referenced chapter represents the best accumulated knowledge for a uniform system of provisions that address the safety and protection of food offered at the retail level.

New Rule IV

The department is proposing to adopt Chapter 3 of the model food code without modifications. The department is proposing this rule because the referenced chapter represents the best accumulated knowledge for a uniform system of provisions that address the safety and protection of food offered at the retail level.

New Rule V

The department is proposing to adopt Chapter 4 of the model food code without modifications. The department is proposing to adopt this rule because the referenced chapter represents the best accumulated knowledge for a uniform system of provisions that address the safety and protection of food offered at the retail level.

New Rule VI

The department is proposing to add minimum potable water tank sizes for mobile food establishments to help ensure an adequate water supply is available for such food establishments. The new rule also provides specific procedures on how to address suspected and contaminated nonpublic water wells serving food

establishments. The department is also proposing this rule because the referenced chapter represents the best accumulated knowledge for a uniform system of provisions that address the safety and protection of food offered at the retail level.

New Rule VII

The department is proposing to promote awareness that food establishment operators may create their own signs or posters, or obtain such signs or posters from a regulatory agency, in light of predatory actions by vendors in other states that have adopted the same or similar sign or poster regulations. The department is also proposing this rule because the referenced chapter represents the best accumulated knowledge for a uniform system of provisions that address the safety and protection of food offered at the retail level.

New Rule VIII

The department is proposing to adopt Chapter 7 of the model food code without modifications. The department is proposing this rule because the referenced chapter represents the best accumulated knowledge for a uniform system of provisions that address the safety and protection of food offered at the retail level.

New Rule IX

The department is proposing to add, modify, and not adopt specific portions of this chapter in the model food code to enable correspondence with existing state law and existing state rules regarding compliance and enforcement.

ARM 37.110.201

The department is proposing to update and clarify terminology, while removing extraneous language from the rule.

ARM 37.110.238

The department is proposing to update and clarify terms with regards to licensing establishments. The department is also proposing to allow regulatory authorities the ability to assess food establishment operations and categorize them into a complexity category for data collection purposes, which may assist in epidemiologic investigations and policy decisions.

ARM 37.110.239

The department is proposing to update and clarify terms, ensure the inspection frequency rule corresponds with existing state law, and remove superfluous language from the rule that is better addressed through department-issued guidance documents, and training of sanitarians by the department or the local regulatory authority.

ARM 37.110.243

The department is proposing to update and clarify terms, ensure the inspection frequency rule corresponds with existing state law, and provide timely reporting of completed inspections to the department by the local regulatory authority.

ARM 37.110.202, 37.110.203, 37.110.204, 37.110.206, 37.110.207, 37.110.208, 37.110.209, 37.110.210, 37.110.212, 37.110.213, 37.110.214, 37.110.215, 37.110.216, 37.110.217, 37.110.218, 37.110.219, 37.110.220, 37.110.221, 37.110.222, 37.110.223, 37.110.225, 37.110.226, 37.110.227, 37.110.228, 37.110.229, 37.110.230, 37.110.231, 37.110.232, 37.110.236, 37.110.240, 37.110.241, 37.110.242, 37.110.252, 37.110.253, 37.110.254, 37.110.255, 37.110.256, 37.110.257, 37.110.258, 37.110.259

The department is proposing to repeal these rules because they will be addressed in the proposed model food code.

Fiscal Impact

There is no fiscal impact due to this rulemaking.

7. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Kenneth Mordan, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail dphhslegal@mt.gov, and must be received no later than 5:00 p.m., July 24, 2014.

8. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

9. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 7 above or may be made by completing a request form at any rules hearing held by the department.

10. An electronic copy of this proposal notice is available through the Secretary of State's web site at <http://sos.mt.gov/ARM/Register>. The Secretary of State strives to make the electronic copy of the notice conform to the official version of the notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the notice and the electronic version of the notice, only the official printed text

will be considered. In addition, although the Secretary of State works to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems.

11. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

12. With regard to the requirements of 2-4-111, MCA, the department has determined that the adoption, amendment, and repeal of the above-referenced rules will significantly and directly impact small businesses.

/s/ Shannon L. McDonald
Shannon L. McDonald
Rule Reviewer

/s/ Richard H. Opper
Richard H. Opper, Director
Public Health and Human Services

Certified to the Secretary of State June 16, 2014.